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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AURINIA PHARMACEUTICALS INC., Plaintiff, v. SUN PHARMACEUTICAL INDUSTRIES, INC.; SUN PHARMACEUTICAL INDUSTRIES, LTD.; and SUN PHARMA GLOBAL FZE, Defendants.	CIVIL ACTION NO: **DEMAND FOR JURY TRIAL**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Aurinia Pharmaceuticals Inc. ("Aurinia") brings this action against Defendants Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries, Ltd., and Sun Pharma Global FZE (collectively "Sun") and hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 101, *et seq.*, arising from Sun's commercial manufacture, use, offer to sell, or sales within the United States, and/or importation into the United States of Sun's CEQUA™ product, a calcineurin inhibitor immunosuppressant ophthalmic solution, prior to the expiration of United States Patent No. 10,265,375 (the "'375 Patent") owned by Aurinia.

THE PARTIES

2. Plaintiff Aurinia is a corporation organized under the laws of Alberta, Canada, having its principal place of business at 4464 Markham Street, Suite 1203, Victoria, BC, V8Z7X8, Canada.

3. Upon information and belief, Defendant Sun Pharmaceutical Industries, Inc. ("Sun USA") is a corporation organized and existing under the laws of Michigan having a principal place of business at 1 Commerce Drive, Cranbury, New Jersey, USA. Upon information and belief, Sun USA is in the business of developing, manufacturing, marketing, distributing and/or selling pharmaceutical products for the U.S. market, including in this judicial district. Sun USA is a wholly owned subsidiary of Sun Pharmaceutical Industries, Ltd. ("Sun India").

4. Upon information and belief, Defendant Sun India is a corporation organized and existing under the laws of India, having a principal place of business

at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, Maharashtra, India; it manufactures more than 2000 products and markets its products globally.

5. Upon information and belief, Defendant Sun Pharma Global FZE ("Sun Global") is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of business at Executive Suite Y-43, P.O. Box 12304, Sharjah, United Arab Emirates. Upon information and belief, Sun Global is a wholly owned subsidiary of Sun India.

JURISDICTION AND VENUE

6. This civil action for patent infringement arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq*. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Sun USA because, among other things, Sun USA conducts business in this District, has availed itself of the rights and benefits under New Jersey law, has committed its acts of patent infringement in the State of New Jersey, and has engaged in substantial and continuous contacts in the State of New Jersey.

8. Upon information and belief, Sun India has had persistent, systematic and continuous contacts with New Jersey as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

9. Upon information and belief, Sun Global has had persistent, systematic and continuous contacts with New Jersey as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

10. Upon information and belief, Sun directly or through an agent, including each other, regularly does or solicits business in New Jersey, engages in persistent courses of conduct in New Jersey, have availed themselves of the rights and benefits under New Jersey law, and/or derives substantial revenue from the development, manufacture, importation, marketing, offer to sell and/or sale of pharmaceutical products throughout the United States, including in New Jersey.

11. Upon information and belief, Sun has consented to personal jurisdiction in this Court for other litigation matters. For example, Sun has consented to personal jurisdiction in *Merck Sharp & Dohme BV et al. v. Sun Pharmaceutical Industries, Inc. et al.*, Case No. 2-20-cv-03007 (D.N.J.). *See also Pfizer Inc. et al. v. Sun Pharma Global FZE et al.*, Case No. 1-19-cv-11746 (D.N.J.); *Celgene Corp. v. Sun Pharma Global FZE et al.*, Case No. 2-19-10099 (D.N.J.).

12. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400.

AURINIA'S PATENT-IN-SUIT

13. The '375 Patent entitled "Ophthalmic Compositions" issued on April 23, 2019. Aurinia is the assignee of the patent. (A copy of the '375 Patent is attached as Exhibit 1.)

BACKGROUND

14. The invention described and claimed in the '375 Patent generally relates to ophthalmic compositions comprising calcineurin inhibitors or mTOR inhibitors, and more particularly to methods for treating an ocular disease and/or condition using the disclosed compositions. '375 Patent, Abstract. Claim 1 of the '375 Patent reproduced below, illustrates the scope of the inventions claimed:

> 1. A pharmaceutical composition comprising:
>
> a calcineurin inhibitor or an mTOR inhibitor;
>
> a first surfactant with an HLB index greater than about 10; and
>
> a second surfactant with an HLB index of greater than about 13,
>
> wherein an absolute difference between the HLB index of the first surfactant and the HLB index of the second surfactant is greater than about 3,
>
> wherein the composition is in the form of mixed micelles having the first and second surfactants; and
>
> wherein the composition contains less than 2% by weight ethanol.

15. Upon information and belief, Sun's CEQUA™ received FDA approval on August 14, 2018. (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210913Orig1s000Approv.pdf). Upon information and belief, CEQUA™ launched

in October 2019 (https://www.businesswire.com/news/home/20191013005028/en/Sun-Pharma-Launches-CEQUA-Treatment-Dry-Eye).

16. Upon information and belief, Sun's CEQUA™ product is manufactured in France by Laboratoire Unither for Sun Global and distributed by Sun USA in the United States (https://cequapro.com/pdf/CequaPI.pdf).

17. Upon information and belief, CEQUA™ is a clear cyclosporine ophthalmic solution to increase tear production in patients with dry eye by delivering the highest FDA-approved concentration of cyclosporine (https://cequapro.com/how-cequa-works/mechanism-of-delivery/). Also, upon information and belief, the delivery system uses NCELL™ technology, a system of self-assembled nanomicelles composed of a blend of polymers, including two surfactants, polyoxyethylene hydrogenated castor oil 40 (Kolliphor® RH 40) and Octoxynol-40. According to Sun, these nanomicelles have an outer hydrophilic layer that allows transport from the aqueous environment of the tear film onto the ocular surface, and an inner hydrophobic core that encapsulates the cyclosporine.

18. Upon information and belief, the CEQUA™ ophthalmic solution is a pharmaceutical composition comprising cyclosporine, which is a calcineurin inhibitor. (https://cequapro.com/pdf/CequaPI.pdf).

19. Upon information and belief, CEQUA™ comprises "…Polyoxyl 40 Hydrogenated Castor Oil…" ("Kolliphor® RH 40"), which is a surfactant with a HLB index of at least 14 (https://cequapro.com/pdf/CequaPI.pdf).

20. Upon information and belief, CEQUA™ further comprises "… Octoxynol-40…" which is a surfactant that has an HLB index of about 18 (https://cequapro.com/pdf/CequaPI.pdf).

21. Upon information and belief, CEQUA™ comprises Kolliphor RH 40 and Octoxynol-40 with an absolute HLB index of greater than about 3 (https://cequapro.com/pdf/CequaPI.pdf).

22. Upon information and belief, CEQUA™ comprises mixed micelles having Kolliphor RH 40 and Octoxynol-40 (https://cequapro.com/pdf/CequaPI.pdf).

23. Upon information and belief, CEQUA™ comprises less than 2% by weight ethanol (https://cequapro.com/pdf/CequaPI.pdf).

24. Upon information and belief, Sun has had knowledge of the patent family that comprises Aurinia's '375 Patent since at least as early as 2016 and was aware of the '375 Patent upon its issuance in April 2019.

FIRST CAUSE OF ACTION
(Infringement of the '375 Patent)

25. Aurinia realleges and incorporates by reference the allegations contained in paragraphs 1-24.

26. Sun has infringed and continues to infringe at least one claim of the '375 Patent, pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, selling, offering to sell or importing CEQUA™ within the United States and without authority.

27. Sun has infringed and continues to infringe at least one claim of the '375 Patent pursuant to 35 U.S.C. § 271(b), literally or under the doctrine of equivalents, by selling and offering for sale in the United States CEQUA™ and instructing end-users through the FDA-approved CEQUA™ Product Label, CEQUA™ instructional materials, CEQUA™ product and technical materials, disseminating CEQUA™ promotional/marketing materials that describe its FDA-approved use for treating dry eye disease, and otherwise instructing end-users to use CEQUA™ to infringe at least one claim of the '375 Patent.

28. At least as of the date hereof, Sun sells and distributes CEQUA™ with the knowledge and specific intent that these instructions will cause end-users to infringe at least one claim of the '375 Patent, and therefore Sun induces end-users to use CEQUA™ in methods that directly infringe at least one claim of the '375 Patent.

29. Sun has infringed and continues to infringe at least one claim of the '375 Patent pursuant to 35 U.S.C. § 271(c), literally or under the doctrine of equivalents, by offering to sell or selling CEQUA™ within the United States for use

by end-users in practicing at least one of the claimed methods of the '375 Patent. CEQUA™ constitutes a material part of the invention of the '375 Patent, and, at least as of the date hereof, Sun knows CEQUA™ to be especially made or especially adapted for use in infringing the '375 Patent. Furthermore, CEQUA™ is not a staple article or commodity of commerce suitable for substantial noninfringing use. Sun sells and offers for sale CEQUA™ with the knowledge and specific intent that its Product Label and other materials as described in paragraphs 17-23 will cause end-users to use CEQUA™ to infringe at least one claim of the '375 patent.

30. Sun's infringement has damaged and will continue to damage Aurinia, which is entitled to recover the damages resulting from Sun's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

31. Moreover, Sun's infringement has caused, and will continue to cause, irreparable injury to Aurinia, for which damages are an inadequate remedy, unless Sun is enjoined from any and all activities that would infringe the claims of the '375 Patent.

32. This case is exceptional, and Aurinia is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Aurinia prays for judgment against Sun, and respectfully requests the following relief:

1. A judgment that the ’375 Patent has been infringed by Sun;

2. A judgment for an injunction enjoining Sun, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling CEQUA™ within the United States, or importing CEQUA™ into the United States prior to the expiration of the ’375 Patent, including any extensions;

3. If Sun continues to commercially manufacture, use, offer to sell, or sell CEQUA™ within the United States, or import CEQUA™ into the United States prior to the expiration of the ’375 Patent, including any extensions, a judgment awarding Aurinia monetary relief together with interest;

4. An award of damages or other monetary relief, including but not limited to costs and pre- and post- judgment interest, and a judgment that the damages so adjudged be trebled pursuant to 35 U.S.C. § 284;

5. Judgment that this is an exceptional case and that Aurinia be awarded its attorneys’ fees incurred in this action pursuant to 35 U.S.C. § 285;

6. Costs and expenses in this action; and

7. Such other and further relief as the Court deems just and appropriate.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38, Plaintiff Aurinia Pharmaceuticals Inc. respectfully demands a jury trial as to all issues so triable.

Respectfully submitted,

Dated: December 18, 2020 By: */s/ Carlos F. Ortiz*

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